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The 'perfect storm' of REACH: charting regulatory controversy in the age of information, sustainable development, and globalization

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The European Union's new chemicals regulation, REACH, has been one of the most controversial pieces of legislation in EU history. Indeed, the debate over REACH is akin to a 'perfect storm' in that the intense controversy over it has been caused by three regulatory aspects of the regime. First, REACH privatizes information collection, provision and assessment. Second, REACH represents a significant application of sustainable development and in so doing, redefines the conditions on which the EU chemicals market operates. Third, REACH will inevitably have inter-jurisdictional impacts for both supranational and national legal cultures including trade law implications, REACH being a template for international initiatives, it being a policy/legal irritant in other jurisdictions, and it providing information for public and private action in other jurisdictions. A charting of these different aspects of the regime not only provides a more nuanced account of REACH but also provides a clearer understanding of the challenges of regulating environmental and health risks in an era of market globalization.

Introduction

In 2001, the European Commission published a White Paper on a Strategy for Future Chemicals Policy (Commission of the European Communities 2001) in which they proposed an innovative approach to chemicals regulation which required the registration, evaluation, authorization and restrictions of chemicals, commonly know as REACH. From that point, until the passing of the final regulation in December 2006, the REACH proposal was one of the most controversial legislative proposals in the history of Community law-making. Debate over it was heated, intemperate and has involved not only regulatory actors within the European Union (EU) but also regulatory actors in other jurisdictions, particularly the USA. Those regulatory actors come from both ends of the political spectrum and have partaken in an intense lobbying process that represents a new era in EU regulatory politics (Persson 2007; Smith 2006).

Looking on from the semi-detached gaze of the legal scholar, the debate over REACH is akin to a 'perfect storm'. Not only is the debate dominated by forceful views but the controversy is due to a range of different issues. Sebastian Junger popularized the concept of a 'perfect storm' in his book of the same name. He wrote:

> Meteorologists see perfection in strange things, and the meshing of three completely independent weather systems to form a hundred year event is one of them. (Junger 2007, 150)

Legal scholars also tend to see perfection in strange things. The perfection I see in the debate over REACH is that it epitomizes the inherent challenges involved in the shift

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to new risk regulatory strategies that reconfigure the role of private actors and the market in the pursuit of the goals of environmental and health protection. In particular, a study of it highlights the way in which market globalization makes that reconfiguration process a particularly polycentric one (Fuller 1978).

In light of this, the purpose of this article is to chart the controversy over REACH before it was passed into law in December 2006. I do so by replacing the polemic and apoplexy that has tended to dominate the REACH debate with a careful charting of the aspects of the REACH regime which made it so controversial. Indeed, just as Junger's perfect storm was the product of three independent weather systems, I see the controversy over REACH being due to three different independent but interdependent regulatory aspects of it. These are: its placing the responsibility for information generation and assessment on private actors; its redefining of the conditions of entry into the market place in pursuit of sustainable development; and the fact that in an era of globalization, it has profound implications for other jurisdictions.

This article is structured as follows. In the first section, I highlight two key features of risk regulation regimes which are important to keep in mind: their controversial nature and that these regimes are embedded in legal and socio-political cultures. Second, I give a brief overview of REACH and in the third section, I examine the innovative and controversial nature of its information requirements. In the fourth section, I analyse the three different aspects that I see have contributed to the furore over the REACH regime. Finally, I consider the lessons that one can take from studying this particular regulatory storm.

Two points should be made before starting. First, I do not pretend that this paper is an exhaustive examination of REACH. My focus is upon the aspect of the regime which gave rise to the most controversy: the information duties placed on market actors. This is not to say that there are not other aspects of REACH which are not important such as the role of the new European Chemicals Agency and the principle of substitution, but these are not the focus of my analysis here. Second, my description of the debate over REACH as a 'perfect storm' should not be understood as my arguing that REACH itself is chaotic or a mess.[1] Rather, my use of the analogy serves to highlight the very intense nature of the debate over REACH as well as the fact that that debate has not been the product of a single set of forces.

Two initial points: the controversial and culturally embedded nature of risk regulation

In studying a regulatory regime that is concerned with the regulation of environmental and health risks, two inherent features of risk regulation must be noted from the start (Fisher 2007, Chapter 1) – that such regulation is controversial and that any regulatory regime is embedded in socio-political and legal culture. It is useful to consider these two points at some length because they highlight the impossibility of untangling chemicals regulation from wider regulatory conflict or jurisdictional culture.

The first of these points to appreciate is that chemicals regulation is inherently controversial. This is for a number of reasons but mainly due to the fact that conflicts over chemicals safety are a classic example of 'risk society' politics in that regulation gives rise to a politics fuelled not only by competing values and scientific uncertainty but also by debates over the way in which risks are distributed, managed

and regulated by a state (Beck 1992 1996). A key feature of this debate has been debate over the legitimacy of regulatory institutions which have been overwhelmingly administrative in nature (Fisher 2007). These debates over legitimacy not only relate to what is an acceptable risk but also to how regulatory institutions 'frame' chemical risk problems and how they assess such risks (Rayner and Cantor 1987; Wynne 2003). As will be seen below and I have discussed elsewhere, these controversies do not dissipate when the role of the state is more marginal due to the utilization of more self-regulatory or market based strategies (Fisher 2006b).

The second feature of chemicals regulation which follows on from the above is that chemicals regulation regimes are inevitably deeply embedded in legal and socio-political cultures (Brickman, Jasanoff, and Iglen 1985; Royal Commission on Environmental Pollution 2003). Such regimes are part of the 'thickness' of such cultures (Fisher 2007; Geertz 1993; Renn and Elliott forthcoming) where the 'thickness' is not simply due to their being different rules but is also to do with the ideas, philosophies and modes of action in operation (Jasanoff 2005; Nelken 1995). Such 'thickness' cannot be captured in comparing the levels of formal protection in a jurisdiction or even comparing regulatory strategies, but can only be understood by studying the ideas, institutions, animating concepts and processes which operate within a particular culture. In particular, chemicals regulation raises difficult questions about the role of the administrative state (Fisher 2007).

These two features of risk regulation have been arguably overlooked in much recent comparative risk regulation literature which has tended to treat regulation in instrumental or 'outcome based' terms (Hammitt et al. 2005; Wiener and Rogers 2002). Appreciating the importance of these two points cannot be overemphasized; however, because what they highlight is that in studying a regulatory storm such as that over REACH, any analysis must be broader than law 'in the books' and its operation. It is for this reason that this article focuses on the debate over REACH rather than its final product as that debate is a means of relating the legal regime of REACH to the socio-political and legal cultures it is embedded in, and other cultures it interrelates with. As we will see below, it is this latter process of interrelationship that is particularly significant in an era of market globalization.

The REACH regime

As noted above, risk regulation is controversial but some regimes are more controversial than others and REACH is the prime example of that. Indeed, REACH is the most controversial piece of European Community legislation ever proposed (Persson 2007; Pesendorfer 2006; Smith 2006). To understand why that is the case, some understanding is needed of REACH itself.

REACH began life in the late 1990s with a review of existing EU chemicals legislation (Commission of the European Communities 1998b) and a commitment to reform it as set out in the 2001 White Paper (Commission of the European Communities 2001, 5). This was followed in 2003 by the publication of a draft regulation (Commission of the European Communities 2003b) and the final regulation was passed into law in December 2006.[2] That regulation is hundreds of pages long and intricately detailed. It formally came into force on 1 June 2007 but the requirement for pre-registration is from 1 June 2008 onwards and the actual process of registration will take place in three stages over 11 years.

The final version of REACH is considerably different from that proposed in the original White Paper and those changes generally represent a weakening of its environmental protection aspects mainly because of the exceptions that have been introduced (Smith 2006). It is useful here to note the regime's main features.[3] First, and most importantly, under the regime an explicit responsibility is placed on producers and importers for both producing information (Article 5) and for ensuring their substances do not adversely affect human health or the environment (Article 1(3)). The former is described as the 'no data, no market' rule which states that registration is required to manufacture or place chemicals on the EU internal market. Central to the process of registration is the submission of a 'technical dossier' which includes information about the chemical, guidance for its safe use, the tests done on it, and a chemical safety report for chemicals produced in more than 10 t (Articles 10 and 14). The substantive annexes to the regulation set out guidance for what needs to be included in that dossier and how assessment should be carried out for the chemical safety report (Annexes I and VI–X). There is also a requirement that manufacturers and importers produce safety data sheets in certain circumstances such as where a substance is persistent, bio accumulative or toxic (Article 31). Even if such data sheets are not required, there is still a need to provide information to downstream users (Article 32). Downstream users also have a duty to communicate information up the supply chain about the hazardousness of the properties and information which might call into question 'the appropriateness of the risk management measures identified in the safety data sheet' (Article 34). Other duties on them include duties to produce safety data reports in certain circumstances (Article 37). As will be seen below, it is these information duties which have caused the most controversy and are the focus of this article. This is because those duties are a regulatory regime unto themselves, although one in which 'public' bodies play no direct role. This is because these duties should lead market actors to adjust their behavior in light of the safety information about risks. However, before this aspect of REACH is further discussed, it is important to understand the entire regulatory regime.

Once registration occurs, then the process of evaluation is entrusted to the new European Chemicals Agency and Member States. In some cases, there is an evaluation *duty* placed on the Agency such as in relation to testing proposals (Article 40) and in others, an evaluation *power* (Article 41). The Agency also has an obligation to produce a rolling action programme for substance evaluation (Article 44) which will result in a coordinated process in which Member States will have a significant role to play (Article 45).

After the process of evaluation is that of authorization. Much of the authorization process follows conventional processes, although a heavy emphasis is placed on substitution and the consideration of alternatives (Articles 55, 60 and 61). An authorization is required for any chemicals included in Annex XIV (Article 56(1)). Substances are included in Annex XIV if they have already been classified by previous directives or if they are found to be: persistent, bioaccumulative and toxic; very persistent and very bio accumulative; or substances for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to substances that are included in Annex XIV (Article 57(f)). The process of identification of substances which fall into Annex XIV is coordinated by the Agency, although Member States may prepare a dossier so as to initiate consideration of a substance (Article 59). The final decision for placing a

substance on the Annex XIV list is by a comitology procedure (Article 133(1)). The actual process of authorization is not by the Chemicals Agency but by the Commission (Article 61), this division of functions reflecting the limitations in delegating power in the EU.[4] The Commission will only grant authorization if 'the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled' (Article 60(2)) where 'adequately controlled' is defined (Article 60(4)). The Commission should also take into account the opinion of the Committee of Risk Assessment (Article 60(2)). If, however, such authorization cannot be granted on this basis, it may be granted if it is shown that the 'socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies' (Article 60(4)). This decision should take into account the opinion of the Committee of Risk Assessment and the Committee for Socio-Economic Analysis.

The Regulation also provides for restricting the manufacturing or placing on the market of dangerous substances (Article 67 and Annex XVII), that is, substances which are held to present an 'unacceptable risk to human health or the environment' (Article 68(2)). There are already a number of substances on this list and the process of including new substances is similar to the authorization process in that it is by a comitology procedure [Article 68(1)] and that there is a role for the Committees of Risk Assessment and Socio-Economic Analysis (Articles 69–73).

What can be seen above is that REACH is a profoundly complex regime which essentially has two aspects: an innovative market based aspect and a more traditional regulatory authorization aspect. Both are significant but it is the former which is really radical (Rogers 2003). The creation and publication of such information will alone have a significant impact on the market for chemicals and as such REACH is a form of 'regulated self regulation' (Hey, Jacob, and Volkery 2006, 12). Not only is the duty to do risk assessments being delegated to private actors but they are also required to publish information so that other private actors, particularly down-stream users, can take action without the need for regulatory intervention. That action may be in many forms and involve consumers, investors and employees (Tietenberg 1998). In other words, the provision of such information will make the market for chemicals work more efficiently. It also may of course result in regulatory action in the form of authorization, but it is the potential response of private actors in the marketplace to information about chemicals which makes the regime so innovative.

Charting the regulatory storm of REACH

While understanding the final regime is important, it is not the issue of direct concern in this article, rather the controversy before December 2006 is. Much of this debate was over the radical information requirements identified above. The important thing to appreciate about these requirements is that they attempted to address a series of fundamental and widely recognized problems in chemicals regulation. Before moving onto the controversy itself, some understanding of those problems is thus needed.

In nearly all jurisdictions, there has been recognition of a need for reform to existing regulatory structures of chemicals regulation (Brickman, Jasanoff, and Iglen

1985; Royal Commission on Environmental Pollution 2003; Winter 2000). The inherently controversial nature of chemicals regulation as noted in the section above is partially a catalyst for such demands for reform but the need for reform also arises out of two features of most chemicals regulation regimes.

First, historically chemicals regulation has tended to be piecemeal in that it has been a series of specific legislative responses to particular problems as those problems emerged. This is particularly the case in the EU context (Commission of the European Communities 1998b; Krämer 2000; Renn and Elliott forthcoming; Royal Commission on Environmental Pollution 2003). The end result is a series of 'fragmented and differentiated' (Royal Commission on Environmental Pollution 2003, 162) regulatory regimes which lack coherence. Indeed, a marked feature of most chemicals regulation regimes is that while 'new' chemicals have received some regulatory attention 'old' chemicals have not. Thus, for example, in the EU, the main regulatory chemical regime before REACH applied to chemicals placed on the market *after* 1981 (Commission of the European Communities 2001) or in other words, to only 1% of the chemicals on the market (Commission of the European Communities 2001, 6). As many of the chemicals started being sold on the market at a time when there was little safety regulation and/or little information about the risks from such chemicals, then such a regulatory focus did not make sense in that there was no logical reason why 'old' chemicals needed less regulation than 'new' chemicals and *vice versa* (Sunstein 1990). Moreover, the old/new risk distinction is also problematic because it means that there are many chemicals on the market for which no proper safety assessment has been done and because it results in an incentive for manufacturers to use old chemicals rather than produce new ones due to the fact that new chemicals will be heavily regulated but old chemicals will not (Commission of the European Communities 2001).

The second related problem with much chemicals regulation is that due to this old/new distinction, there is very little comprehensive information about the health and environmental risks of chemicals that have been on the market for a long time (Denison 2007). In part, this is due to the normal problems of scientific uncertainty which plague technological risk regulation in that even if data is available about a chemical, the assessment of that data is fraught with difficulties (Fisher 2000; Stirling 2003). More significantly, however, the lack of information is due to the fact that, without regulation, there have been few incentives on manufacturers of chemicals to produce and disperse information about the health and environmental safety of chemicals. Indeed manufacturers of chemicals have strong incentives to externalize the cost of the production of information (Applegate 2006; Wagner 2004). Such information is essentially a 'public good' and its production not only holds few benefits for manufacturers but also considerable costs (Breyer 1982; Ogus 1994). This problem will be discussed in more detail below, but here it is worth noting that those costs are not only in information production but also if such information identifies problems with a chemical. This leads to a paradoxical situation in that as Wagner notes:

> actors who create externalities are best situated to access and produce information on the nature of the harms that their activities cause, but they also stand to lose from providing such information. (Wagner 2004, 1648)

Moreover, the problem is made even more difficult in that the value of information cannot be known until it is actually generated (Lyndon 1989, 1810). Lack of

information not only makes regulation difficult but also means that the market for chemicals cannot work efficiently (Stephan 2002; Tietenberg 1998). This lack of information cannot easily be solved with requiring regulatory authorities to produce such information as they simply do not have the resources to do so (Commission of the European Communities 2001; Royal Commission on Environmental Pollution 2003). Thus in systems where regulators do have the power to regulate, the process of assessing chemicals has often been very slow (Ahlers 2000; Renn and Elliott forthcoming).

In light of the above, the search for better ways to regulate chemicals has been a constant theme in chemicals regulation literature in the last decade. In particular, and not surprisingly, there has been an increasing emphasis on the importance of information disclosure on the part of private actors (Bernson 2000; Korrkainen 2001; Stephan 2002) including information disclosure along the supply chain (James et al. 2007). Moreover, this emphasis on information is consistent with the 'new' regulatory philosophy which has dominated risk regulation policy and scholarship over the last decade (Fisher 2006b; Lenschow 2002; Scott and Holder 2006). In particular, there has been a shift away from command and control strategies towards deploying self-regulatory, market based strategies which integrate economic competitiveness with social goals (Fisher 2006b; Lenschow 2002; Levi-Faur 2005). These new strategies have often been promoted as 'smarter' and less conflict-bound approaches to regulation when compared to traditional command and control (Gunningham and Grabosky 1998). Moreover, because they are seemingly less state focused, they seem more apt for an era of globalization where the state appears to be increasingly irrelevant (Fisher 2006b).

In other words, the information requirements of REACH are not only a regulatory response to widely recognized problems in chemicals regulation but those requirements are consistent with cutting edge regulatory strategies. Those strategies have often been promoted as being more win–win in nature but in relation to REACH, they gave rise to controversy far greater than any other regulatory initiative. Indeed, the REACH proposal is infamous for giving rise to a fundamentally new lobbying politics in the EU (Pesendorfer 2006; Smith 2006) and the Commission was 'flooded' with submissions from a range of regulatory actors from all parts of the political spectrum although most significantly from industry (CEFIC 2003a; Contiero 2006; Montfort 2003; Persson 2007, 228–30). For industry organizations, it was 'economic suicide by a massive self-administered regulatory overdose' (Logomasini and Miller 2005, 13), while for environmental non-governmental organizations, the amended regime was worth three out of ten (Green 10 2007, 27). A striking feature of this new politics was that it did not remain within EU borders but also involved transnational actors (Persson 2007, 233–4) and particularly US government and US industry (Committee on Government Reform - Minority Staff Special Investigations Division 2004). Moreover, the REACH proposal also led to the proposal of similar US initiatives.[5]

Analysing the perfect storm

The reality is that since December 2006, the REACH debate has seemingly blown itself out. This is not to say that it is no longer controversial but that with its passing into law its legitimacy is naturally no longer a matter of debate.[6] Yet while the

regulatory seas are now becalmed, the features of the regime which were the source of controversy remain. While the regulatory storm can partly be understood as due to the fact that, as seen in the first section, chemicals regulation is innately controversial, it is more significantly due to three regulatory features of the REACH regime: the privatization of information provision and assessment; the rewriting of the conditions of the market; and the fact that it will have an impact on other jurisdictions.

In this section, I consider each of these issues at some length. As will be seen, each of these issues is separate and in that sense, the debate over REACH can really be understood as a series of sub-debates. At the same time, however, it will also become clear that the controversies over each of these issues are interrelated. The perfect storm is thus more than a sum of these sub-storms.

Privatizing information provision and assessment

The first aspect of why REACH has proved so controversial is that it places on private actors obligations to produce, assess, publicize and communicate information where no significant obligations existed before. Thus while industry has often needed to supply some information to regulatory authorities (Conrad 2006; Rogers 2003), the obligations under REACH are significantly greater, involving duties of testing, risk assessment, data sharing and communication with downstream users. Thus while Article 5 is described as the 'no data, no market rule', the obligations placed on private actors amount to far more than that.

The privatization of information is a departure from the historical situation where the duty to collect and assess information about the health and safety risks from chemicals has been on regulators, although private actors have often been a significant source of information. The heavy reliance on administrative bodies has not only overburdened them (Royal Commission on Environmental Pollution 2003) but also has led to a politics concerning the validity of regulators acting on different types of information (Fisher 2006a; Hood, Rothstein, and Baldwin 2001). In particular, there has been the development of specific methodologies for regulatory information assessment and collection such as risk assessment and regulatory impact assessment (Fisher 2000; Jasanoff 1986).

REACH represents a significant internalization of the costs of producing information about chemical safety, particularly because it operates as a precondition to entry into the internal market. As noted above, this process of internalization is arguably just remedying a market distortion (Ogus 1994) and by requiring the provision of such information, the market for chemicals should work more effectively. Thus while REACH does also have an evaluation and authorization dimension, much of the regulation will arguably occur through the market. At the same time, the REACH regime still makes heavy use of risk assessment and other analytical methodologies (Royal Commission on Environmental Pollution 2003).

The privatization of information provision and assessment is acutely controversial for numerous reasons, which can be loosely grouped into three overlapping categories. First, there are ideological concerns with REACH. From the perspective of industry, this form of privatization is internalizing a cost they have historically not had to bear and regulating products which have been virtually unregulated. As such, REACH has been strongly criticized as another form of regulatory red tape, the cost

of which is too great (Caplan 2006; Logomasini and Miller 2005). There is an irony in this criticism because REACH does represent a shift away from more bureaucratic command and control forms of regulation. In contrast, many green groups have also seen REACH as not involving aggressive enough action on the part of regulators (Green 10 2007; Pesendorfer 2006). Some of the debate over REACH is thus a dispute between those who are pro- and anti-regulations where the debate is heightened due to the fact that much of this area has been unregulated for so long and the result of regulation is to place quite specific but non-traditional obligations onto manufacturers.

The second set of controversies relates to debates over whether this type of information provision and assessment is a workable regulatory strategy. In other words, will the creation of obligations of information provision and assessment actually work and if so for what purpose? As Stephan has pointed out, the theoretical basis for these types of strategies is unclear and the justifications for placing such burdens on private actors are not only economic but are also to do with democracy and more general legitimacy concerns (Stephan 2002). The workability of such strategies is still open to question particularly because in the technological risk regulation arena, information provision and assessment strategies have tended to be relatively small scale (Karkkainen 2002; Tietenberg 1998) and REACH represents the first major regulatory information disclosure initiative. Moreover, the increasing reliance on this type of private actor assessment as a regulatory tool has been questioned in some quarters particularly from those working in the accounting field where such techniques originated (Power 1997). It is not clear whether these techniques deliver real accountability in that the quality of the data can be difficult to assess (Rose 1999).

The third set of reasons for why information provision and assessment are controversial is to do with the practicalities of it. As Tietenberg has noted, in designing an information disclosure regime, decisions need to be made about how risks are to be identified, how the quality of information is to be assured, how information is to be publicized and shared, and how that information is to be acted on (Tietenberg 1998). Each of these issues has proved controversial in relation to REACH. Thus there has been considerable debate over the heavy reliance on risk assessment rather than hazard assessment (CEFIC 2003c; Hansen 2006). Likewise, critics have noted that the regime places 'strong trust' in the willingness of private actors to do assessments properly (Pesendorfer 2006). The information sharing aspects of REACH have also been problematic from a commercial confidentiality perspective (Stanton 2005) and there have been concerns that the information produced will lead to irrational action on the part of regulators and the public (Durodie 2003). More significantly, there have also been a number of critics who argue that REACH places too great a reliance on traditional tools of risk assessment rather than on more effective information assessment techniques and regulatory strategies (Koch and Ashford 2006; Royal Commission on Environmental Pollution 2003; Scheringer, Boschen, and Hungerbuhler 2006). Indeed, REACH is giving rise to a new debate about the utility of risk assessment. It is new because it is a debate which is considering that utility outside the normal province of risk assessment – the administrative state (Fisher 2006a).

As stressed above, these different points of controversy are overlapping and they all highlight the fact that while the privatization of information provision and

assessment may be legitimate, it is also likely to give rise to fierce debate. Furthermore, the controversy over information provision has also been intensified by two misnomers which have been frequently raised in the REACH debate and which in their own right are controversial. The first is that REACH has been argued, even by the Commission itself (Commission of the European Communities 2001, 5), to be an application of the precautionary principle. Indeed, Article 1(3) of the REACH regulation describes the provisions of the Regulation as being 'underpinned by the precautionary principle'. While the precautionary principle is a legitimate principle, it is also fiercely debated (Fisher, Jones, and von Schomberg 2006). Moreover, while some of the aspects of authorization could be understood as precautionary (Renn et al. 2003), there is, as Heyvaert has shown with careful analysis, little in REACH which would not have been included 'but for' the precautionary principle (Heyvaert 2005). This is because the real reform of REACH is in the provision of data and not in the process of risk evaluation. This is not to say that the precautionary principle does not have a background role to play but only so far as the collection of more information in circumstances of scientific uncertainty aids better precautionary decision-making (Deville and Harding 1997). Indeed, as will be shown in the next section, REACH has far more to do with the concept of sustainable development than with the precautionary principle.

The second misnomer that has created confusion in debate is the idea that REACH 'shifts the burden of proof' in relation to information provision (Rogers 2003). This description has been popular on the Community institutions websites, although it is not contained in the Regulation where reference is only to a general information burden in the Preamble (paras 25, 30 and 33). The concept of 'shifting of a burden of proof' is a legal one but from a legal perspective, this description of the privatization of information provision and assessment is problematic for two reasons. First, the legal concept of the burden of proof in its most general sense refers to a reasoning strategy in cases where there is a particular dispute (Fisher 2007; Gaskins 1992). In regard to REACH, however, the privatization of information provision and assessment is not a reasoning strategy but rather it is a precondition for entry into the market. Second, from a legal perspective, the burden of proof usually operates in the bipolar context of a legal trial. The role of such burdens is to allocate both the responsibilities for the production of evidence and the risk of errors if a trial does not produce truth (Stein 2005). In contrast, in the REACH context, the privatization of information provision and assessment is operating in the polycentric fields of the market place and regulation. In these circumstances, decision-makers are not just deciding between two parties but making complex decisions in which they are active participants (Fisher 2007). Moreover, within the adjudicative context, 'it is for the parties to determine whom and what [judges and juries] they see or hear, but not how they evaluate and reason from evidence' (Twining 1994, 194–5). This again is not the case in either the regulatory context or in relation to operators in the market place.

The point about these different controversies over the information aspects of REACH is that they were inevitable. As noted in the first section, the information gap in relation to chemicals has been well recognized as has the fact that it has been caused by a 'rectifiable problem' (Royal Commission on Environmental Pollution 2003, 164). The appreciation of that fact alone is not enough to quell controversy, however. The issue has also been made more complicated by the fact that the use of

the language of the precautionary principle and the burden of proof has resulted in a misunderstanding about the nature of REACH. This has meant that debate over REACH has overlapped with debates about those other controversial issues, the REACH regime is presumed to contain elements it does not contain, while at the same time, the quite radical aspects of the regime are overlooked.

Pursuing sustainable development

The second reason for why REACH has proved particularly controversial is in relation to the fact that it represents an application of the concept of sustainable development. This is because the privatization of information provision and assessment represents a redefining of the conditions for entry into the market where that redefinition is designed to ensure a high level of environmental and health protection. REACH thus represents the integration of environmental and economic concerns, this type of integration being integral to the ideal of sustainable development (Dovers and Connor 2006; Dryzek 2005).

The reconciliation between environmental protection and the market economy was a central aim of REACH from the outset (Commission of the European Communities 2001, 4) and that aspiration is reflected in the Preamble to the Regulation (paras 3 and 4) as well as Article 1(1) which states that:

> The purpose of this Regulation is to ensure a high level of protection of human health and the environment…as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

This dual purpose is in other provisions of the regulation (Article 55). Moreover, that purpose is evidenced in the fact that the REACH regulation was passed under the internal market competence (Article 95 TEC), that within the Commission, it required negotiation between DG Environment and DG Enterprise, and that there was debate in the Council over whether the Environmental Council or the Competitive Council should take the lead in debates (Pesendorfer 2006; Smith 2006).

The concept of sustainable development is not new in the EU polity. It is included in the Treaty establishing the European Community (Articles 2 and 6 TEC), the Treaty on European Union (Article 2 TEU) and the Charter of Fundamental Rights (Article 37).[7] It has also been the main focus of the last two environment programs,[8] its own separate strategy (Brussels European Council 2005), and the Cardiff process on integration of environmental concerns into other areas of decision-making (Commission of the European Communities 1998a 2004). Furthermore, REACH is also understood to further the aims of the related Lisbon strategy which aims to increase innovation in the EU and the competitiveness of European industry (Dimas 2005; Lisbon European Council 2000). In other words, REACH is embedded in a series of different policies and strategies aimed at integrating environmental and economic concerns.

REACH promotes this type of integration by greater information disclosure and assessment which allows the market to work more efficiently in relation to chemicals which pose health and environmental risks. That is, with greater knowledge of the effects of chemicals, the market should work so that those chemicals which pose environmental and health risks will not be competitive. This in itself is a spur to innovation but REACH also promotes innovation by creating parity of treatment between old and 'new' chemicals so that the cost of the introduction of 'new'

chemicals is not out of proportion with the cost of continuing to use old chemicals. Furthermore, the authorization aspect of the REACH regime constantly encourages the consideration of alternatives (Articles 55, 60, 61 and Annex XV), and authorization requires application of the principle of substitution (Articles 55, 60 and 61), these being further catalysts to innovation. Indeed, REACH can be understood as an example of reflexive law that attempts to harness the self-referential capacities of economic actors working in a market place (Gaines 2002; Orts 1995). Overall, REACH should promote a more efficient, innovative and competitive marketplace which will achieve a higher level of health and environmental protection than before. It is thus a good example of attempts to put ideas of ecological modernization into action (Weale 1993).

As with the privatization of information provision and assessment, there are many reasons why the explicit pursuit of sustainable development is controversial. The first set of reasons for it being so have concerned whether the costs of REACH to private actors exceed the public benefits. A number of impact assessments were conducted by both Community institutions and others as part of the process of debate and the results of these assessments were themselves queried (Commission of the European Communities 2003a; Fraunhofer ISI et al. 2005; KPMG 2005). This has resulted in a sub-politics concerned with the legitimacy of impact assessment as a regulatory technique and also highlights the difficulties of making these types of assessment (Pearce and Koundouri 2004). This last point is particularly significant as it suggests that an operational presumption of much of the REACH debate, that the impact on economic development can be assessed, is not correct.

The second set of reasons why the sustainable development aspect of REACH has proved controversial has concerned whether environmental and economic concerns can be properly integrated. In particular, there are those that have been concerned about the balance between the environmental and economic imperatives. As seen above, some have argued that the economic costs are too great (Logomasini and Miller 2005), while there are those who have argued that REACH places too much emphasis on economic concerns at the cost of environmental protection (Contiero 2006; Pesendorfer 2006). Moreover, there are some who have argued that increased costs of registration will impact on research and development (Wolf and Delgado 2003). The issue of what is a correct balance between environmental protection and economic growth is notoriously difficult and the debate over REACH reflects deeper tensions operating within the concept of sustainable development (Redclift 1987). Moreover, it also highlights the realities of trying to integrate the two into public decision-making (Jewell 1998, 79–80). The fact that the European chemical industry is understood to be an 'economic cornerstone' of the internal market has been added to the stakes in this debate (Stanton 2005).

The final set of reasons for the controversial nature of REACH is to do with how the requirements of registration regulate the market. Historically, most environmental regulation operates as a limit on market activity, 'you can do what you like but not *x*'. Such laws dictate what particular kinds of behavior are not allowed. In contrast, registration is operating as a precondition to market activity: without registration, a manufacturer cannot even begin to operate in the Community market. Moreover, the information requirements of registration are resulting in the production of information which is making the market work more effectively. In

other words, REACH is playing a constitutive role in that it regulates who can participate in the market and on what basis they do so. As Levi-Faur notes:

> Regulation is both a constitutive element of capitalism (as the framework that enables markets) and the tool that moderates and socializes it (the regulation of risk). (Levi-Faur 2005)

As noted above, most environmental laws fall into Levi-Faur's latter category but REACH is part of the former category because registration is part of the framework for a market. The significance of this is twofold.

First, REACH is a distinct departure from other techniques of environmental regulation not just because it is 'innovative' or 'market-based' but because its role is far more to do with creating the market than just regulating it. While reconstituting markets is at the heart of the sustainable development agenda, there have been relatively few examples of it actually occurring in practice. Second, REACH as a law concerned with the constituting of the market is a reminder that markets are social constructions whose existence owes much to state action (Egan 2001; Fligstein 2001). The significance of this reminder is not particularly great in the EU where it has always been appreciated that the internal market is a creation of legal and political forces (Egan 2001; Fligstein 2008; Fligstein and Maro-Dita 1996; Maduro 1998). It is more radical, however, in those jurisdictions where markets have tended to be understood as domains of action that exist before the state. Moreover, such reminders are reminders that both law and markets are creation of particular legal and socio-political cultures (Fligstein 2001; Nelken 1995). Regimes such as REACH are not playing purely functional roles but are deeply embedded in ways of economic and legal thinking in a specific jurisdiction. Thus, for example, some critics of REACH have argued that it is problematic because it represents a 'socialist orientated regulatory model' that is part and parcel of a planned economy (Kogan 2005, 99).

Inter-jurisdictional impacts of REACH

The culturally embedded nature of REACH is profoundly significant for the last aspect of REACH which has been a source of acute controversy, its inter-jurisdictional aspect. By being a significant legislative initiative on the part of a jurisdiction with a large market, REACH will *prima facie* have implications for other jurisdictions. This is particularly because the international trade in chemicals is significant and the industry is dominated by a number of multinationals (Royal Commission on Environmental Pollution 2003, 5). In having this inter-jurisdictional impact, it will specifically have implications for a diverse range of actors with different interests who will also wish to influence the nature of REACH. This can be seen most obviously with US chemical industry lobbying attempts (Committee on Government Reform, Minority Staff Special Investigations Division 2004). Chemicals regulation is not only polycentric (Fuller 1978) but polycentric in a way that is both embedded in legal cultures as well as stretching beyond them. Those interested in reform are thus not only having to address the concerns of local regulatory actors whose points of views have been shaped by the legal and political conditions in that culture but also the views of actors in other jurisdictions whose concerns are similarly shaped by their own local conditions.

With that said, it is important to appreciate that the inter-jurisdictional impacts of REACH are not limited to one particular type of impact. Rather, at least four different types of impacts can be identified. The first is that by its very nature, REACH has implications for international trade in that a regulatory regime is, by itself, a non-tariff barrier (Sykes 1999). This is even where a major feature of the REACH regime is information provision (Hilson 2005). In particular, it has been argued from some quarters that REACH breaches Article 2.2 of the WTO TBT Agreement (CEFIC 2003b), although the EU has argued that REACH is WTO compliant.[9] The point about these debates is that the issue of WTO compliance is uncertain not just because there has been not much relevant WTO 'jurisprudence' on this point but also because understandings of WTO jurisprudence are still emerging (Steinberg 2004). In particular, actors are still struggling with the idea that dispute settlement is a normative enterprise that involves a ruling on the legitimacy of national administrative and regulatory arrangements (Fisher 2007, chapter 5). The WTO system is thus still evolving itself and debates about REACH are contributing to that evolution process just as other disputes have (Fisher 2007, chapter 5).

The second inter-jurisdictional impact that REACH is having is that it provides a blueprint for international initiatives in relation to chemicals regulation. Over the last decade, there have been both public and private initiatives to increase knowledge and action in relation to chemicals at the international level. These include the chemical industry's Responsible Care program, OECD initiatives and the Strategic Approach to International Chemicals Management which was a product of the 2002 Johannesburg Summit on Sustainable Development (Royal Commission on Environmental Pollution 2003, chapter 3). The European Commission explicitly stated in the 2001 White Paper that one of the purposes of REACH was to influence these international debates (Commission of the European Communities 2001, 9). Thus the close interrelationship between REACH and the voluntary Strategic Approach to International Chemicals Management (SAICM) has been recognized. SAICM which was agreed at Dubai in 2006 has very similar aims in relation to substitution and information provision that REACH has.[10] Likewise, there are implications for both the OECD's chemical safety initiatives and the chemical industry's 'Responsible Care' program (Pesendorfer 2006; Royal Commission on Environmental Pollution 2003; van der Kolk 2000). This use of EU environmental regulation as a starting point for international regulatory initiatives is not new and has been recognized by political scientists as a growing trend. Kelemen has gone so far to argue that the EU has engaged in a process of 'offensive management' of the pressures of globalization in promoting their regulatory regimes (Kelemen 2007). Such promotion is a form of globalization management because by having their regulatory system being adopted at a global level, a jurisdiction can gain economic and political advantages as well as ensuring that international law obligations do not frustrate national goals (Busch, Jorgens, and Tews 2005). This form of regulatory competition is particularly significant when one considers that, as seen above, initiatives such as REACH are deeply embedded in different legal and economic cultures. The competition is thus not just a competition between techniques or levels of protection but between different constructions of the role of law and the nature of the market place.

The third inter-jurisdictional impact that REACH has is upon chemicals regulation in other jurisdictions. Regulatory policy networks operate across

jurisdictions and as many scholars have shown, regulatory initiatives in one jurisdiction tend to lead to a process of legal/policy transfer in other jurisdictions, a form of 'contagious diffusion' (Levi-Faur 2005, 23). The key feature of this process of diffusion is that it does not lead to a process of convergence but rather a process of 'divergent convergence' (Legrand 1998; Levi-Faur 2006). In other words, initiatives such as REACH act as catalysts for regulatory reform in other jurisdictions but the nature of that reform is dependent upon the unique circumstances of that other culture. REACH is thus a potential irritant rather than a potential transplant (Cotterrell 2001; Levi-Faur and Jordana 2005). As an irritant, it is a catalyst for a process of reflection, debate and reform, but those processes may take many different forms. Thus, for example, as seen above, REACH has led to not only a revival of the debate about reform in the USA but also the proposal of regulatory initiatives (Applegate 2006; Tickner, Geiser, and Coffin 2005). Those debates have, however, been more about reforming US legislation rather than importing European legislation.

The final inter-jurisdictional impact of REACH is due to the information it will produce. As noted above, the information produced by private actors will be publicly available and that availability will also be in other jurisdictions. What this means is that the information from REACH may be the catalyst for public and private action in other legal cultures. That action may be in how individuals participate in the market but it also may take the form of regulatory action or private law actions (Tietenberg 1998, 591–2). In this case, it is the information produced by REACH, rather than REACH itself which is the irritant.

Reflecting on the perfect storm

The discussion above goes a long way to moving discussion about REACH considerably beyond the polemic and apoplexy which has marked the debates over the regime. It has done so by charting the reasons for that intense debate. As such, what is clear from the analysis above is that REACH is not only a very complex regime but that much of the controversy is not misplaced. REACH is controversial because the strategies it is deploying are controversial. This is not to say that these strategies are not legitimate and indeed what is clear is that the internalizing of the cost of the public good of information provision and assessment is a much needed reform (Lyndon 1989).

What I wish to do in this last section is to consider what general lessons or conclusions can be taken from such an analysis. While the process of reflecting on REACH is a multidimensional one, there are three basic conclusions that are particularly significant for thinking about other environmental regulation reform. The first, as already noted, is that the intense controversy over REACH was inevitable but that does not mean that REACH is an illegitimate regulatory strategy. In other words, the existence of debate and conflict over REACH actually tells us very little about the validity of the regime. This conclusion is particularly important in an era in which the shift to more market based regulatory strategies is understood to be a shift to 'win–win' environmental solutions (Gunningham and Grabosky 1998). The conflict which has marked more traditional forms of technological risk regulation does not disappear with the utilization of more 'innovative' regulatory strategies (Fisher 2006b). Rather, as the debate over

REACH highlights, it can even become greater because of the uncertainties concerning how such strategies do, and should, work. Even while in the long run, a regulatory strategy may achieve both environmental protection and economic growth, that 'win–win' outcome may be difficult to assess and the institutional/cultural barriers to change are significant. In other words, an analysis of REACH highlights the need to probe more carefully the relationship between the conflict over legislative proposals and their legitimacy. No-one can pretend that such inquiry is not a fraught and tortuous one.

Second, with that said, the passing of REACH shows that reform is possible in an area which has been widely recognized as needing reform but in which little action has been taken (Lyndon 1989; Royal Commission on Environmental Pollution 2003). The recent Canadian reforms in this area are also significant in this regard although they take a different institutional format in that they rely heavily on public administration (Denison 2007). Whether these are 'good' reforms is of course a matter for debate but the radical nature of REACH cannot be denied. It represents a redefining of the responsibilities of public and private actors and a reconstituting of the market place. Thus despite the conflict charted above, real change has occurred. Just as the radical nature of some environmental law reforms should not create a presumption of their legitimacy, likewise their radical nature should not mean that there is a presumption that they are not possible to bring into force. Of course, the operation of REACH is sure to bring its own lessons just as the operations of the US Toxic Substances Control Act 1976 (Applegate 2006; Renn and Elliott forthcoming), or Superfund (Hird 1994), or EU risk regulation regimes (Vos 1999), have brought theirs. It is simply too early, however, to consider those lessons and proper reflection on REACH's operation will only be possible after a long period of full implementation. In particular, it will be interesting to see how the process of private information provision works in practice and how useful information in the form of risk assessments is.

The third and most significant conclusion to be taken from this charting of the REACH storm is in relation to the inherent tension between the culturally embedded nature of regimes such as REACH and the inter-jurisdictional impact that they have. I say tension because this is a conflict between the cultural particularity of a regulatory regime and the strong pressure for the application of such a regime in other jurisdictions. REACH represents a redefining of the market, an activity which is not seen as unusual in the EU because, as seen above, the market is a creation of law and the state. Thus while REACH is radical, it is not as radical in the EU as it would be in other jurisdictions where the market is understood as being quite separate from state activity. Much of the reaction to REACH is thus a reaction to the EU conceptions of the role of the state in the market place (Kogan 2005). This is particularly the case in the USA where the presumption is that the market does not depend for its existence on the state. The dominant focus in recent years has thus been on whether the benefits of market interference outweigh the costs (Sunstein 2002) rather than upon how a state fashions a market. De-regulation has also been a theme (Fligstein 2008). The problem of course is that the impact of REACH is not confined to the EU. As seen above, REACH is both a blueprint for policy reform at the global level and is an irritant for policy reform in other jurisdictions. The point is that the irritant is not just the regulatory strategy itself but the legal and socio-political culture it is embedded in.

It is this process of transferring not just regulatory techniques but also regulatory cultures which is becoming an increasing feature of technological risk regulation. Indeed, REACH itself encompasses US legal irritants such as risk assessment and cost/benefit analysis and the debate over its legitimacy also encompassed regulatory impact analysis (Fisher 2006a; Wiener 2006). Examples can be seen in other areas of European regulation being grounded in US regulatory ideals, particularly with regard to regulatory impact assessment (Baldwin 2005; Radaelli 2005; Wiener 2006). As already noted, this process is not straightforward in that a regulatory idea transferred from one jurisdiction to another is more a policy or legal 'irritant' than a straight transplant and in so being leads to often unexpected regulatory developments in other jurisdictions (Legrand 1997; Levi-Faur 2005). The overall point is that in thinking about environmental regulation, one can neither presume the generality nor the specificity of regulatory techniques. Legal systems are neither fully sealed off nor totally porous. As Jasanoff and Long Martello have noted, the globalization of the environmental agenda has led to a 'rediscovery of the local' (Jasanoff and Long Martello 2004, 4).

The key point about these three conclusions is that they add new dimensions to thinking about technological risk regulation and its reform, particularly in an era in which sustainable development is a dominant ideology. In particular, they force a greater engagement with culture without necessarily negating the possibility of reform and that reform having an impact upon other jurisdictions. In other words, a study of the REACH debate leads one back to my initial starting point about risk regulation, that it is controversial and that it is culturally embedded.

Conclusions

As Junger pointed out, the 'perfect storm' at the center of his book was a product of a set of weather and geographical conditions unique to that part of the Grand Banks (Junger 2007, 149). At the same time, weather in one place is also closely interrelated with weather in other locations (Junger 2007, 100–4) both in being caused by weather in those other locations and also leading to knock on effects. The same is also true of regulatory reforms such as REACH. REACH is a product of, and embedded in, EU legal and regulatory culture. In particular, it is a regime which by internalizing the costs of information provision and assessment is reconfiguring the internal market. Such a reconfiguration is consistent with community concepts of market building, but REACH also has profound implications for other jurisdictions in that it reflects a proper attempt to deal with some real problems in chemicals regulation and because such large scale regulatory initiatives in an era of globalization must have an impact beyond their jurisdiction.

Moreover, just as a study of perfect storms gives meteorologists an understanding of how storms operate both in the past and in the future, so too does a study of the debates over REACH give us some understanding about the challenges faced in technological risk regulation. In particular, such a study highlights the conflict-bound nature of those reforms, the fact that despite that being the case, reform can happen, and finally that regulation is always caught between being specific to a legal and socio-political culture and being a regime with global impact. The experience of REACH thus forces a reflection on much of the present technological risk regulation discourse.

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Notes

1. Compare my use of the perfect storm analogy to that of Bergkamp and Smith in their discussion of the 'tidal wave' of EU safety legislation (Bergkamp and Smith 2004).
2. Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC OJ [2006] L396/1 and Directive 2006/121/EC of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances in order to adapt it to Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency OJ [2006] L396/850.
3. For a more detailed analysis, see Hansen (2006).
4. Article 7 TEC and Case 9/56 *Meroni v. ECSC High Authority* [1957–8] ECR 133.
5. H.R. 4308/S. 1391 Child, Worker and Consumer Safe Chemicals Act introduced July 2005 but was never passed.
6. As the REACH regime is slowly phased in, new controversies are likely to appear, albeit on a different scale. For example the litigation challenging the validity of certain aspects of the regime. See *R(on the application of SPCMA SA and ors) v The Secretary of State for Environment, Food and Rural Affairs* [2007] EWHC 2610 and the subsequent preliminary reference filed with the European Court of Justice (see Case C-558/07, reference for a preliminary ruling from the High Court of Justice (Queen's Bench Division) Administrative Court (UK) made on 17 December 2007 – *R(on the application of SPCM. SA and others) v Secretary of State for Environment, Food and Rural Affairs.*
7. Note that at present, the Charter has no legal force.
8. Decision No. 1600/2002/EC of the European Parliament and of the Council of 22 July 2002 laying down the Sixth Community Environment Action Programme [OJ] 2002 L242/1 and Decision No. 2179/98/EC of the European Parliament and of the Council of 24 September 1998 on the review of the European Community program of policy and action in relation to the environment and sustainable development 'Towards sustainability' [OJ] 1998 L275/8.
9. Response from the European Communities to Comments Submitted by WTO Members Under G/TBT/EEC/52 (Regulation Concerning REACH COM (2003) 644 Final.
10. See paras 14 and 15 of the Overarching Policy Strategy for SAICM.

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